

## REMARKS/ARGUMENTS

In the office action dated July 23, 2007, the Office rejected claims 14-23. In response, claims 1-24 have been canceled and new claims 25-34 are added. Applicant maintains that no new matter has been added.

### **35 U.S.C. 102 Rejection**

Claims 14, 15, 17-23 were rejected under 35 U.S.C. 102(b) as being anticipated by De Santis (US 5,560,373) and Shaw (US 5,261,818). Applicant respectfully traverses this rejection in view of the new claims herein.

New Claim 25 recites “A drill bit for drilling hard tissue and injecting medication comprising:...” and now includes the limitation “wherein an overall length from a distal tip of the cutting surface to a proximal end of the open notch is greater than the thickness of the hard tissue”. No new matter has been added. The “overall length” limitation is taken from para [0038] as reinforced by para [0039] and Figures 3b, and 10b. The utility of having a combined length greater than the hard tissue’s thickness is illustrated in Figures 5a, 5b, 12a, and 12b where medication can be delivered before, during, and after drilling of a target tissue (see para [0043]).

Regarding previously pending Claims 14, 15, 17, 18, 22, and 23 and De Santis, the Applicant acknowledges that De Santis teaches a biopsy needle or cannula having a shaft, a lumen, and a notch for use in collecting soft tissue samples (C7/L67); however, De Santis does not teach a “drill bit for drilling hard tissue and injecting medication”. Nor does De Santis teach a drill bit having an open notch and a beveled cutting surface where “an overall length from a distal tip of the cutting surface to a proximal end of the open notch is greater than the thickness of the hard tissue” (emphasis added). Rather, De Santis illustrates that up to the entire length of the biopsy needle can penetrate the target tissue (Figure 12a), and therefore the overall length from the distal tip of cutting surface to the proximal end of the notch (open notch) must be less than the target tissue’s thickness as opposed to greater than the target tissue’s thickness.

Regarding new Claims 25, 26, 28 and 30-34 and Shaw, the Applicant agrees that Shaw teaches a dental drill bit having an irrigation channel (lumen) and outlets. However, the applicant disagrees that Shaw teaches the drill bit as having “...a lumen inside the shaft ... that

receives debris entering the first opening as a result of operation of the cutting surface;” (emphasis added) as recited in new Claim 25. In fact, Shaw teaches away from the lumen receiving debris, by reciting an “irrigation channel 18 having input 20 and a plurality of outlets 22...” (C2/L33-34). By design, the Shaw irrigation channel (lumen) flushes debris away from the working tip (cutting surface) along the co-axial channels (notch). Therefore, the Shaw lumen does not “receive[s] debris entering the first opening as a result of operation of the cutting surface”. Additionally, Shaw also fails to teach, suggest, or motivate “an overall length from a distal tip of the cutting surface to a proximal end of the open notch is greater than the thickness of the hard tissue”.

Claims 26 and 28-34 are allowable by virtue of their dependency on Claim 25.

### **35 U.S.C. 103 Rejection**

Previously pending Claim 16 was rejected under 35 U.S.C. 103(a) as being obvious over De Santis (US 5,560,373) and Shaw (US 5,261,818). Applicant respectfully traverses this rejection in view of amendments herein and the following discussion.

With respect to Claim 16, the Examiner argues that spacing of the notch at 0.10 to 0.125 inches is merely a design choice over De Stantis or Shaw. The stated rationale is that the “Application has not disclosed that the specific distance provides an advantage, is used for a particular purpose, or solves a stated problem.”

The Applicant respectfully disagrees. The Applicant has included specific reasoning for the recited spacing within the specification. The specified spacing is to ensure that the length of the bevel cutting surface plus the length of the open notch is greater than the thickness of cortical bone or other hard tissue. Specifically, para [0038] states:

“The length of the open slot plus the length of the bevel should always be larger than the thickness of the targeted cortical bone and/or hard tissue. For intraosseous applications using a 24G drill bit, for example, the slot 18 is about 0.10 to 0.125 inch measured from the distal tip to the proximal end of the slot, as shown as distance 19 in FIGS. 2 and 3b.”(emphasis added).

Para [0039] reinforces having a range for the spacing by stating:

“The length from the sharpened tip to the open notch 38 should always be larger than the thickness of the targeted cortical bone and/or hard tissue. For intraosseous applications using a 24G drill bit, for example, the notch or hole 38 is about 0.10 to 0.20 inch measured from the distal tip to the center of the notch or hole, as shown as distance 39 in FIGS. 9 and 10b.” (emphasis added)

The above passages coupled with Figures 5a, 5b, 12a, and 12b, illustrate that having sufficient spacing to overcome the thickness of the hard tissue ensures that the “medication delivery device ...stays unclogged by debris” as fully described in para [0043] and para [0044]. Therefore, the problem solved by the spacing is to keep the device from becoming clogged with debris during drilling. The advantage of the spacing is that the “...beveled tip stays open during and after drilling through the target tissue...” (emphasis added, para [0044]). Finally, the particular purpose of the spacing is to “...continue [to] serve as a medication delivery passage...” (para [0044]) to administer medication.

Given the above arguments, the obviousness rejection of Claim 16 as being a mere design choice should be withdrawn. Nevertheless, in the spirit of cooperation the Applicant has added Claim 25 which recites that the “overall length...is greater than the thickness of the hard tissue”, and has added new Claim 27 to recite “the overall length is about 0.10 to 0.125 inches” to clarify the connection between the specified range and the utility of the drill bit when used on hard tissue.

### **Request For Allowance**

Claims 25-34 are pending in this application. The Applicant requests allowance of all pending claims.

Respectfully submitted,  
Fish & Associates, PC

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By: /Robert D. Fish/  
Robert D. Fish  
Reg. No. 33880

Fish & Associates, PC  
2603 Main Street, Suite 1000  
Irvine, CA 92614-6232  
Telephone (949) 943-8300  
Fax (949) 253-9069